



PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference XXX	FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/AN2004/000142	International filing date (day/month/year) 20.05.2004	Priority date (day/month/year) 19.03.2004	
International Patent Classification (IPC) or national classification and IPC INV. C07H1/06 C07H5/02			
Applicant PHARMED MEDICARE PRIVATE LIMITED			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 43 sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 18.10.2005		Date of completion of this report 17.07.2006	
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized officer de Nooy, A Telephone No. +31 70 340-2338 	

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**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IN2004/000142

Box No. I Basis of the report

1. With regard to the language, this report is based on

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements* of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-23 as originally filed

Claims, Numbers

1-23 as originally filed

24, 25 received on 03.11.2005 with letter of 18.10.2005

Drawings, Sheets

1-6 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☒ the description, pages 1-27
- ☒ the claims, Nos. 26-31
- ☒ the drawings, sheets/figs 7,8
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-23
	No: Claims	24,25
Inventive step (IS)	Yes: Claims	1-23
	No: Claims	24,25
Industrial applicability (IA)	Yes: Claims	1-25
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

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**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

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Re Item I

Basis of the report

Amended claims 24 and 25 are considered allowable since in the original description (page 4 lines 9-16, page 23 lines 11-14) it is explicitly stated that the products from the process be amorphous or non-crystalline.

All other amendments however, being page 7 the description of the two extra figures, the extra material of pages 23-26, new claims 26-31 and new figures 7 and 8 are considered not-allowable (Rule 70.2(c) PCT) since in the original application there is no basis for those amendments. There can be no basis for new figures since those figures cannot be exactly the same as a text, therefore, the content of those figures cannot have been present in the original application. The new added pages as well as the new claims 26-31 are also considered to extent the scope of the original application because the addition of particle sizes was not present at all (only one remark, page 23 line 14) where it is stated that the powders have smaller particle size. However, no numbers are specified, therefore, any added number is considered unallowable added matter.

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following documents:

D1: P.H. Fairclough et al. Carbohydrate Res. 40 (1975) 285-298

D2: US4380476

Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of newly filed claims 24 and 25 is not new in the sense of Article 33(2) PCT.

The documents D1 and D2 disclose the synthesis and isolation of sucralose, thus claims 24 and 25 lack novelty since a product by process must be new and inventive. A product is not rendered novel merely by the fact that it is produced by a new process. Moreover, both D1 and D2 disclose non crystalline sucralose (D1 page 293, sucralose was obtained as a syrup; D2 column 10 line 14 as a syrup) therefore, claims 24 and 25 are considered not

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novel.

Inventive step

The present claims 1-23 meet the criteria of Article 33(1) PCT in the sense of Article 33(3) PCT.

The document D1 is regarded as being the closest prior art to the subject-matter of claims 1-23, and discloses the synthesis and isolation of sucralose

The subject-matter of claims 1-23 differs from this known subject matter in that a drying step or super critical extraction step as in claim 1 is included. Furthermore, a deacetylation of intermediates of chlorinated sucrose is performed before as well as after said drying step.

The problem to be solved by the present invention may therefore be regarded as the provision of further processes for the synthesis and isolation of sucralose.

The solution proposed in claims 1-23 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons.

It is not obvious for the skilled person to include a drying step as in claim 1 and to perform a deacetylation before as well as after said drying step. In D1 there is no incentive to do so.